MAIL STOP NON FEE AMENDMENT
Attorney Docket No. 24301

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

TOMKA et al.

Serial No.: 09/606,219 Group Art Unit: 1772

Date Filed: June 29, 2000 Examiner: NORDMEYER, P.

Title: **A METHOD FOR MANUFACTURING A SHAPE BODY CONTAINING A STARCH, A HOMOGENISED MASS CONTAINING STARCH AND A DEVICE FOR MANUFACTURING A SOFT CAPSULE**

RESPONSE TO OFFICIAL ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Official Action dated August 4, 2003 in the captioned application, which has a three (3) month period for response. Accordingly, a Petition for a One-Month Extension of Time is filed herewith, along with the requisite fee. Thus, this Response is timely filed.

Claims 12-21 and 23-32 are currently pending in the present application. In view of the following remarks, applicants respectfully request the Examiner to reconsider and withdraw the outstanding rejections and allow the claims pending in this application.

1. Rejection of claims 12, 14, 17, 23 and 24 under 35 U.S.C. §102(b)

The Official Action states that claims 12, 14, 17, 23 and 24 stand rejected under 35 U.S.C. §102(b) as being anticipated by Stroud (US Patent No. 5,554,385). In particular, the Official Action states the following in relevant part:

> Stroud discloses a soft capsule (Col. 1, lines 41-42), wherein the capsule is made from 3-60% high amylose starch, 30% glycerol (a softener) and 6% water (Col. 4, lines 59-63) that is homogenized (Col. 3, lines 22-25). Amylopectin makes up 50% of the starch (Col. 2 lines 17-28). Since Stroud contains the selected materials of amylopectin and glycerol, it is inherent that the starch would have a viscosity between 40 ml/g and 60 ml/g.

Applicants respectfully traverse this rejection. The Stroud reference fails to teach all of the limitations of the presently claimed invention, and thus, cannot be a novelty-destroying reference against the presently pending claims.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the

claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Claims 12, 14, 17, 23 and 24 are drawn to a mass comprising at least 45% by weight of an amorphous starch, water, and at least one organic softener in at least 12% by weight with respect to the weight of the water-free starch, wherein the mass is a homogenised mass having a limiting viscosity index of at least 40ml/g and wherein the starch has an amylopectin content of greater or equal to 50% by weight with respect to the weight of the starch in water-free condition and is obtainable from native or chemically-modified starch.

In contrast, Stroud teaches a gelatin capsule sheath in which a portion of the gelatin is replaced with a high amylose content starch to provide a dry capsule sheath having 3-60% by weight high amylose starch wherein the amylose content of the starch is at least 50% and preferably 90% high amylose starch. Stroud does not teach a homogenised mass with an amylopectin content of at least 50% by weight, water and an organic softener and having a limiting viscosity index of at least 40ml/g.

The Examiner states in her rejection that because "Stroud contains the selected materials of amylopectin and glycerol, it is inherent that the starch would have a viscosity between

40 ml/g and 60 ml/g." Applicants respectfully disagree. To show the Examiner that the starch taught by Stroud does not inherently have a viscosity between 40 ml/g and 60 ml/g, applicants attach herewith a Declaration under 37 C.F.R. 1.132 prepared by one of the inventors of the captioned application, Rico Ménard. In the Declaration, Mr. Ménard attests that he supervised the preparation of the capsules as they were prepared by Stroud according to Example 3 of the '385 patent. Upon completion of the preparation of the molten mass, the limiting viscosity was measured in accordance with the DIN standard DIN 51562 as taught in the present application and a limiting viscosity index of 23 ml/g was obtained. Thus, contrary to the Examiner's assertion, it is not inherent that the teachings Stroud would result in a starch that has a viscosity between 40 ml/g and 60 ml/g.

Further, the present claims are drawn to homogenised mass, such as a soft capsule, that is made from a completely gelatin-free mass. In contrast, Stroud's claims are directed to a soft gelatin capsule. Stroud only suggests replacing a part (up to 85%) of the gelatin by a starch. (See. Col. 2, lines 47-49). Accordingly, Stroud does not provide a composition for the manufacture of shape bodies in which the commonly used gelatin has been completely substituted.

Further, the present claims require that the starch has an amylopectin content of greater than or equal to 50% by weight with respect to the weight of the starch in water-free condition. In contrast, Stroud suggests replacing a portion of the gelatin by a high amylose starch, i.e. a starch having an amylose content of at least 50% and those having 90% or more is most preferred. (See col. 2, lines 26-28). Thus, there is only a slight possible overlap with Stroud with regards to the amylopectin content when there is exactly 50% amylose and 50% amylopectin, albeit in the presence of gelatin.

Thus, each and every element as set forth in the presently pending claims has not been found, either expressly or inherently, in Stroud as required by *Verdegaal Bros. v. Union Oil Co. of California.* Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the present rejection of claims 12, 14, 17, 23 and 24.

2. Rejection of claims 13, 15-16, 18-21 and 25-32 under 35 U.S.C. §103(a)

The Official Action states that claims 13, 15-16, 18-21 and 25-32 have been rejected under 35 U.S.C. §103(a).

a. The rejection of claims 18-20 and 28-32 as being unpatentable over Stroud

In particular, claims 18-20 and 28-32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stroud (USPN 5,554,385). Regarding claims 18-20 and 28-32, the Official Action states the following:

> Stroud discloses a soft capsule (Col. 1, lines 41-42), wherein the capsule is made from 3-60% high amylose starch, 30% glycerol (a softener) and 6% water (Col. 4, lines 59-63). Amylopectin makes up 50% of the starch (col. 2, lines 17-28) in the capsule, which has a thickness of 0.03 inch (col. 3, lines 44-45). Since Stroud contains the selected materials of amylopectin and glycerol, it is inherent that the starch would have a viscosity between 40 ml/g and 60 ml/g. However, Stroud fails to disclose an elongation of rupture of at least 100%, preferably at least 160%, and even more preferred 240% at 25 C and 60% relative air humidity, the body shape with a strength of at least 2 MPa, preferably a strength in the range of 3.5 MPa to 8 MPa and even more preferred from 4 MPa to 6.5 MPA and a capsule with a thickness between 0.1 and 2 mm, preferably between 0.2 and 0.6 mm.
>
> One of ordinary skill in the art would have recognized the claimed capsule would have an elongation rupture of at least 100%, preferably at least 160%, and even more preferred 240% at 25 C and 60% relative air humidity, the body shape with a strength of at least 2 MPa, preferably a strength in the range of 3.5 MPa to 8 MPa and even more preferred from 4 MPa to 6.5 MPA since Stroud teaches a soft capsule containing the same parameters as the claimed invention. Therefore, one of ordinary skill in the art would readily determine the optimum strength and elongation of rupture depending on the desired end results in the absence of unexpected results.

> Stroud discloses the claimed invention except for the thickness of the capsule. It would have been obvious to one having skill in the art at the time the invention was to have a wall thickness between 0.2 and 0.6 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 220 F.2d 454, 105 USPQ 233 (CCPA 1955).

Applicants respectfully traverse this rejection. The reference of record does not teach or suggest applicants' inventive subject matter as a whole as recited in the claims. Thus, the Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Claims 18-20 and 28-32 are drawn to a shape body, in particular a soft capsule casing manufactured from a mass comprising at least 45% by weight of an amorphous starch, water, and at least one organic softener in at least 12% by weight with respect to the weight of the water-free starch, wherein the mass is a homogenised mass having a limiting viscosity index of at least 40ml/g and wherein the starch has an amylopectin content of greater or equal to 50% by weight with respect to the weight of the starch in water-free condition and is obtainable from native or chemically-modified starch.

In contrast, and as stated above with regards to the rejection of claims 12, 14, 17, 23 and 24 under 35 U.S.C. §102(b) over this identical reference, Stroud teaches a gelatin capsule sheath in which a portion of the gelatin is replaced with a high amylose content starch to provide a dry capsule sheath having 3-60% by weight high amylose starch wherein the amylose content of the starch is at least 50% and preferably 90% high amylose starch.

Stroud does not teach a homogenised mass with an amylopectin content of at least 50% by weight, water and an organic softener and having a limiting viscosity index of at least 40ml/g.

The Examiner states in her rejection that because "Stroud contains the selected materials of amylopectin and glycerol, it is inherent that the starch would have a viscosity between 40 ml/g and 60 ml/g." Applicants respectfully disagree. In order to show the Examiner that the starch does not inherently have a viscosity between 40 ml/g and 60 ml/g, applicants attach herewith a Declaration under 37 C.F.R. 1.132 prepared by one of the inventors of the captioned application, Rico Ménard. In the Declaration, Mr. Ménard attests that he supervised the preparation of the capsules as they were prepared by Stroud according to Example 3 of the '385 patent. Upon completion of the preparation of the molten mass, the limiting viscosity was measured in accordance with the DIN standard DIN 51562 as taught in the present application and a limiting viscosity index of 23 ml/g was obtained. Thus, contrary to the Examiner's assertion, it is not inherent that the teachings Stroud would result in a starch that has a viscosity between 40 ml/g and 60 ml/g.

Further, the present claims are drawn to homogenised mass, such as a soft capsule, that is made from a completely gelatin-free mass. In contrast, Stroud's claims are directed to a soft gelatin capsule. Stroud only suggests replacing a part (up to 85%) of the gelatin by a starch. (See. Col. 2,

lines 47-49). Accordingly, Stroud does not provide a composition for the manufacture of shape bodies in which the commonly used gelatin has been completely substituted.

Further, the present claims require that the starch has an amylopectin content of greater than or equal to 50% by weight with respect to the weight of the starch in water-free condition. In contrast, Stroud suggests replacing a portion of the gelatin by a high amylose starch, i.e. a starch having an amylose content of at least 50% and those having 90% or more is most preferred. (See col. 2, lines 26-28). Thus, there is only a slight possible overlap with Stroud with regards to the amylopectin content when there is exactly 50% amylose and 50% amylopectin, albeit in the presence of gelatin.

Accordingly, Stroud does not teach or suggest all the limitations of the presently pending claims as required by *In re Wilson*. As such, the Examiner has failed to make a *prima facie* case of obviousness. Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection.

b. The rejection of claims 13, 16 and 27 as being unpatentable over Stroud in view of Overholt

The Official Action states that claims 13, 16, 27 stand

rejected under 35 U.S.C. §103(a) as being unpatentable over Stroud (USPN 5,554,385) in view of Overholt (USPN 6,258,380). Regarding claims 13, 16 and 27, the Official Action states the following:

> Stroud discloses the claimed invention above except for the mass additionally containing a lubricant and releasing agent selected from the desired group, the mass containing an aggregate in a weight range between 3.5% and 15% from the desired group and the aggregate weight range being between 5 and 8% by weight.
>
> Overholt teaches a plasticizer, lubricant, made from glycerin, sorbitol or maltitol (col. 7, lines 48-50) and an aggregate chosen from cellulose, vegetable gums, saccharides and silicon dioxide (col. 7, lines 54-58) in a weight percent of 0.5 to 6.5% (col. 7, lines 59-61) in a sheath of capsule for the purpose of making a sheath of a soft capsule that has a non-sticky consistency and is flexible.

Applicants respectfully traverse this rejection. The references of record do not teach or suggest applicants' inventive subject matter as a whole as recited in the claims. Thus, the Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims.

As stated above, Stroud does not teach or suggest all the limitations of the presently pending claims as required by *In re Wilson*. Overholt does not remedy the deficiencies of the Stroud reference.

Overholt does not teach or suggest a homogenised mass

with an amylopectin content of at least 50% by weight, water and an organic softener and having a limiting viscosity index of at least 40ml/g. Nor does Overholt teach that the starch has an amylopectin content of greater than or equal to 50% by weight with respect to the weight of the starch in water-free condition. Further, Overholt does not teach soft capsules formed from a gelatin-free, starch-containing mass. To the contrary, Overholt suggests a combination of two specific gelatins together with a plasticizer and a moisture retaining agent.

Accordingly, the Stroud and Overholt references do not teach or suggest all the limitations of the presently pending claims as required by *In re Wilson*. As such, the Examiner has failed to make a *prima facie* case of obviousness. Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection.

c. The rejection of claims 15, 25 and 26 as being unpatentable over Stroud in view of Nakajima et al.

The Official Action states that claims 15, 25 and 26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stroud (USPN 5,554,385) in view of Nakajima et al. (USPN 5,098,606). Regarding claims 15, 25 and 26, the Official Action states the following in relevant part:

> Stroud discloses the claimed starch mass except for the mass containing glycerine monostearate and lecithin in a weight ratio of 1:1.5, preferably 1:1.2, and even more preferred 1:1.
>
> Nakajima et al. teaches a phospholipid, lecithin and glycerine monostearate as a nonionic surfactant in a ration of phospholipid to surfactant of 9.5:0.5 to 1:9 in an emulsified composition used for the administration of drugs for the purpose of incorporating the drug quickly into the body from the blood stream of the patient.

As stated above, Stroud does not teach or suggest all the limitations of the presently pending claims as required by *In re Wilson*. Nakajima et al. do not remedy the deficiencies of the Stroud reference.

Nakajima et al. do not teach or suggest a homogenised mass with an amylopectin content of at least 50% by weight, water and an organic softener and having a limiting viscosity index of at least 40ml/g. Nor do Nakajima et al. teach that the starch has an amylopectin content of greater than or equal to 50% by weight with respect to the weight of the starch in water-free condition. Further, Nakajima et al. do not teach soft capsules formed from a gelatin-free, starch-containing mass.

In contrast Nakajima et al. is not even related to shape bodies such as soft capsules. Also, contrary to the Examiner's assertion, Nakajima does not refer to glycerine monostearate but to POE glycerine monostearate which is

polyoxyethylene glycerine monostearate, which is not the lubricant referred to in claims 13 and 15 of the present application.

Accordingly, the Stroud and Nakajima et al. references do not teach or suggest all the limitations of the presently pending claims as required by *In re Wilson*. As such, the Examiner has failed to make a *prima facie* case of obviousness. Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection.

d. The rejection of claim 21 as being unpatentable over Stroud in view of Patel et al.

The Official Action states that claim 21 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Stroud (USPN 5,554,385) in view of Patel et al. (USPN 6,248,363). Regarding claim 21, the Official Action states the following:

> Stroud discloses the claimed starch mass except for the mass containing the shape body consisting of a multi-layered film and that at least two of the layers have different chemical composition.
>
> Patel et al. teach multi-layered film, multi-coating on soft capsules made of different materials for the purpose of delivering pharmaceutical active ingredients to the user of the capsule.

As stated above, Stroud does not teach or suggest all the limitations of the presently pending claims as required by *In*

re Wilson. Patel et al. do not remedy the deficiencies of the Stroud reference.

Patel et al. do not teach or suggest a homogenised mass with an amylopectin content of at least 50% by weight, water and an organic softener and having a limiting viscosity index of at least 40ml/g. Nor do Patel et al. teach that the starch has an amylopectin content of greater than or equal to 50% by weight with respect to the weight of the starch in water-free condition. Further, Patel et al. do not teach soft capsules formed from a gelatin-free, starch-containing mass.

In contrast, Patel et al. teach a pharmaceutical composition in the form of solid carrier comprising a substrate and an encapsulation coat on the substrate.

Accordingly, the Stroud and Patel et al. references do not teach or suggest all the limitations of the presently pending claims as required by *In re Wilson.* As such, the Examiner has failed to make a *prima facie* case of obviousness. Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections of claims 12-21 and 23-32. Favorable action with an early allowance of the claim pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,

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Date: December 4, 2003
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